

Message

From: Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALITA, JENNIFER]
Sent: 11/17/2020 3:59:49 PM
To: Rodan, Bruce [rodan.bruce@epa.gov]
Subject: FW: PFBS
Attachments: OPPT Review of ORD PFBS Document_11-09-2020_SIGNED.pdf

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

DC
Cel

Ex. 6 Personal Privacy (PP)

From: Jones, Samantha <Jones.Samantha@epa.gov>
Sent: Wednesday, November 11, 2020 1:18 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>
Cc: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: RE: PFBS

Hi Jennifer,

I am concerned with these last minute comments from OPPT considering the following:

OVERARCHING: OPPT commented on the draft PFBS assessment during the final Agency and Interagency review stage prior to us sending the revised assessment to IOAA for final clearance. These comments were not raised during that time (or in previous reviews).

Additionally, prior to this, when the assessment was revised after public comment and it was decided that we would go for another round of external peer review, the charge questions, highlighting the BMR as well as the uncertainty factors, were circulated for review by the Agency and Interagency reviewers (late Dec 2019/early Jan 2020). No comments or recommendations were received at that time on these two topics. We subsequently underwent a second external peer review with agreement with the decisions presented in the latest version of the assessment.

REGARDING THE BENCHMARK RESPONSE (BMR): A 20% BMR was used in earlier drafts of the assessment for the thyroid hormone changes; however, based on comments from the public raising some questions around the confidence in the 20% BMR and the recommendation to use the standard deviation approach statistically recommended for continuous data (like thyroid hormone changes), we adjusted the PFBS assessment, went through agency and interagency review of the charge questions (as noted above) and then a second round of external peer review, as well as final agency and interagency review, all with agreement on this approach. It would have been helpful to hear more about the Endocrine Disruptor Screening Program statement regarding a 20% BMR that seems to be viewed as guidance in the comments during the multiple engagements within the Agency.

REGARDING THE DATABASE UF: OPPT was asked to comment on PFBS assessment to provide perspective on whether OPPT would apply such uncertainty factors within OPPT under the Toxic Substances Control Act (TSCA). OPPT disagreed with the application of the database UF but it is unclear why they would weigh in on this since it isn't considered or applied in the TSCA chemical risk evaluations;

Ex. 5 Deliberative Process (DP)

ORD routinely considers the evidence base for a chemical and whether to apply a quantitative value for the database

uncertainty factor in all of its assessments that develop reference values. The application in PFBS is consistent with practices in those assessments and has been rigorously reviewed by agency (including OPPT), interagency, and external peer reviewers. To change now would undermine those previous processes.

I am forwarding these comments to the team so that we can dig in further especially regarding the dismissal of the 3-fold application of a database UF for the absence of a developmental neurotoxicity. I don't agree with the outright dismissal noted by OPPT but would like to confer with the assessment leads and discuss the PFBS evidence base and considerations in light of these comments.

I'll note that it is unlikely that they will see this email since today is a holiday and they will not be checking email.

Thanks,
Samantha

Samantha J. Jones, PhD
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From: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Sent: Wednesday, November 11, 2020 11:45 AM
To: Jones, Samantha <Jones.Samantha@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>
Cc: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: FW: PFBS

See attached and let me know asap whats up here. I thought they had previously signed off

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DC Ex. 6 Personal Privacy (PP)
Cell

From: Dunlap, David <dunlap.david@epa.gov>
Sent: Wednesday, November 11, 2020 11:33 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: FW: PFBS

Jennifer,

As you and I are aware, OPPT reviewed the draft GenX assessment and provided some recent comments to OW (as they are the lead on the GenX assessment). I had distributed those GenX comments to ORD's PFBS team for awareness. It seems, in light of those GenX concerns, OPPT decided to review and comment on the PFBS assessment. See attached.

Not exactly sure how these concerns can be resolved, but I do know that our first real discussion about these concerns should not occur in front of the Administrator. So I suggest two immediate actions:

- Postpone Thursday's PFBS discussion with the Administrator (we can still meet and review the GAO draft response), and
- Set up a meeting with OCSPP to discuss their PFBS concerns and a potential resolution.

Thoughts?

DDD

David D. Dunlap
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From: Fischer, David <Fischer.David@epa.gov>
Sent: Tuesday, November 10, 2020 11:34 AM
To: Hoverman, Taylor <hoverman.taylor@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Ross, David P <ross.davidp@epa.gov>
Subject: RE: PFBS

All, OPPT developed the appended document on UFs for PFBS; as you will see, OPPT would have used a different UF value for data insufficiency. Thanks.

David

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